

Start Planning Early



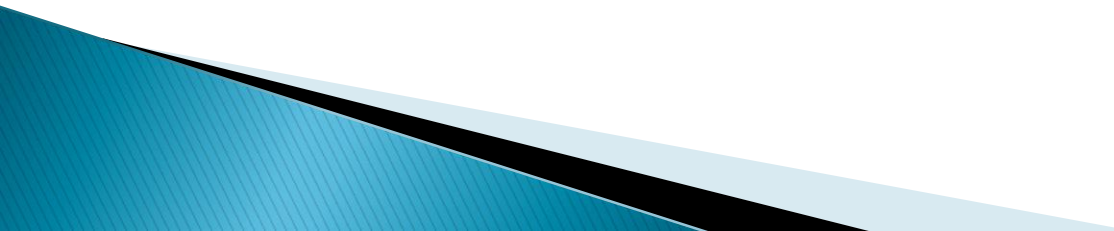
Clinical Center Experience

- ▶ To date, trials that need to submit results have been small
- ▶ Investigators/Departments have established their own databases

Planning

- ▶ Know what information you need to collect

Know what information you need to collect

- ▶ Baseline Characteristics
 - ▶ Outcome Measures (Results)
 - ▶ Adverse Events
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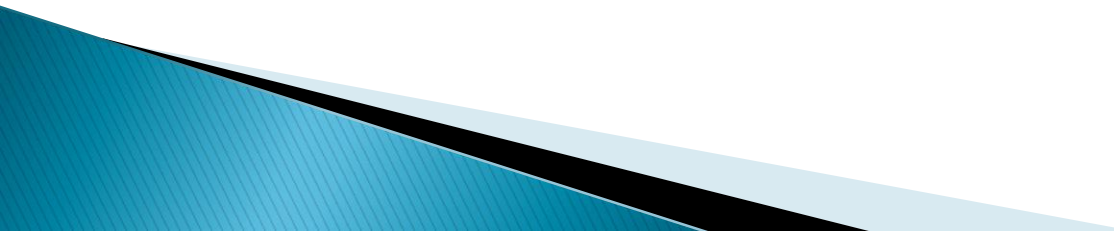
Planning

- ▶ Know what information you need to collect
- ▶ Create ways to collect the results you will report

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- ▶ Make sure to collect the data you have to submit
- ▶ Can the database generate reports that will give you the data you need?

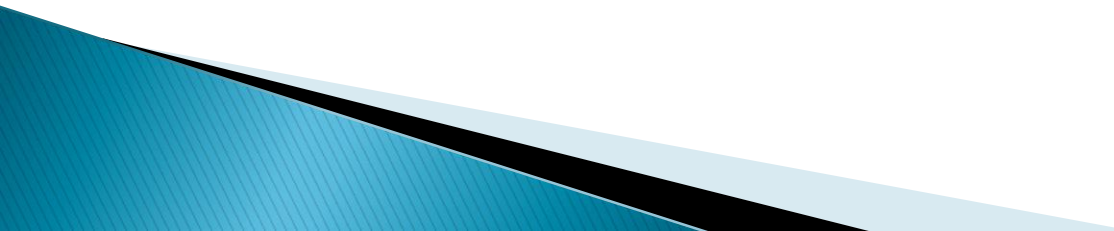
Planning

- ▶ Know what information you need to collect
 - ▶ Create ways to collect the results you will report
 - ▶ Identify the data you need to collect
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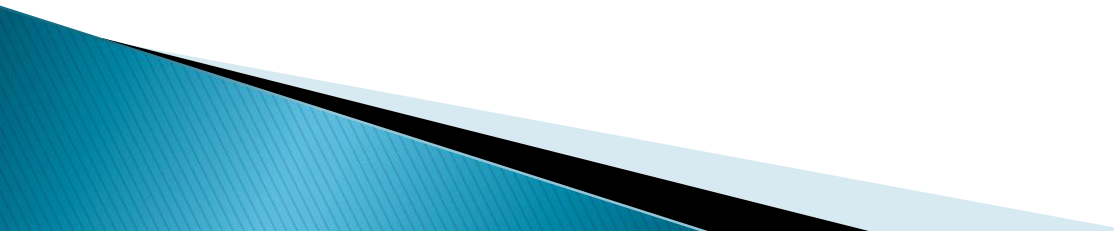
Identify the data you need to collect—Outcome Measures

- ▶ Know your protocol's Primary Objective and what data you will have to report

Data to Report

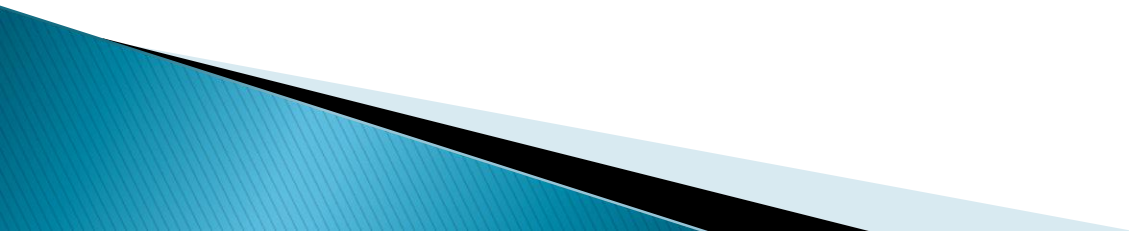
- ▶ To evaluate the effect of Drug X followed by Drug Y on biochemical PSA progression at 6 months
 - ▶ The incidence of *C. difficile* diarrhea at 30 days post broad spectrum antibiotic use
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Identify the data you need to collect

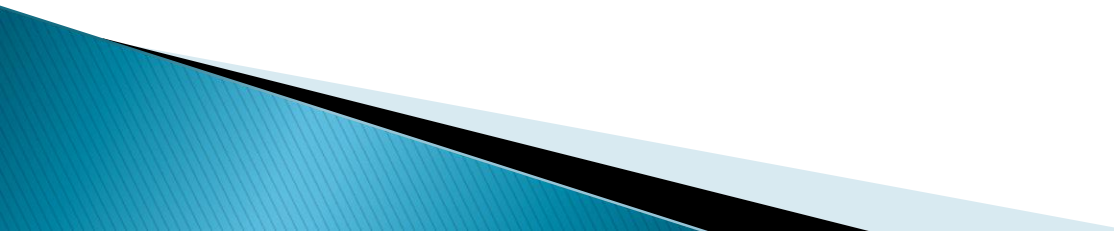
- ▶ Know your protocol's Primary Objective and what data you will have to report
 - ▶ Refine the Primary Objective or create specific outcome measures early on if the Primary Objective is too broad
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May need to refine

Investigate the contributions of cell-associated and secreted miRNA species from resident and inflammatory lung cells in healthy subjects and during the initiation and resolution of acute lung inflammation following segmental lung challenge with Drug Z in healthy volunteers



Identify the data you need to report—Adverse Events

- ▶ Collect them
 - ▶ Create your tables when you collect the data
 - ▶ Be familiar with the terms/organ systems that you have to use (MedDRA)
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Start Planning Early

- ▶ Know what you need to collect
- ▶ Design effective ways to collect the information from the very beginning

